Introduction to ISO 14971 Medical Devices Risk Management

Course Description

This one-day training course helps medical device professionals gain an understanding of how ISO 14971 can improve their business and risk management efforts.

Participants will also understand how ISO 14971 applies to ISO 13485. The training includes exercises, and participants will have the chance to ask questions about how ISO 14971 and risk management apply to their organizations.

Course Benefits

You will gain an understanding of the impact that ISO 14971:2009 has on the decision making process when manufacturing medical devices.

Learning Objectives

On completion of this training, participants will be able to:

- Identify the links between ISO 13485 (QMS) and ISO 14971 (RM)
- Explain how risk management relates to the product lifecycle
- Define risk management terminology
- Outline the stages of the risk management process
- Define the key deliverables of the risk management process

Intended Audience

- Regulatory, quality, design (including design changes), development, manufacturing, marketing managers and personnel
- Decision makers on management system strategy
- Internal auditors

Course Duration

1 Day

Agenda

Time	Topic
9:00	Introduction
	Delegate introductions
	Boundaries: Conflict of Interest and Expertise
	Overview of course structure and learning objectives

	Learning Objectives
	Intended Audience
	Risk Management - Introduction
	ISO 14971 - Overview, Including the Six Phases of Risk Management
	Links from 14971 to 13485, and Regulations
	Risk Analysis
	Risk Evaluation
	Risk Control
	Evaluation of Overall Risk Acceptability
	Risk Management Report
	Production and Post-Production Information
	Review and Final Thoughts
5:30	Final Questions